Cardoplus® 50

Losartan Potassium and Hydrochlorothiazide
film coated tablet

DESCRIPTION:

Cardoplus® 50 combines a nonpeptide angiotensin II (A-II) receptor antagonist and a thiazide diuretic, hydrochlorothiazide. It is used to treat high blood pressure. It blocks the action of certain chemicals that tighten the blood vessels, so blood flows more smoothly. It also causes the kidney to get rid of excess water and salt from the body into the urine.
Losartan potassium is orally active and it binds competitively and selectively to the A-II subtype-1 (AT_1) receptor, thereby blocking A-II induced effects. This leads to decrease vasopressor activity and aldosterone secretion. The active metabolite of losartan, a carboxylic acid derivative, contributes substantially to its antihypertensive effect which persists for 24 hours following once daily administration.
Hydrochlorothiazide has a complex mechanism of action, including natriuresis and vasodilation. Reduction in blood volume brought about by hydrochlorothiazide activates the main angiotensin system (RAS). It also decreases serum potassium, as a result of its diuretic effects. Administrations of losartan blocks the activation of RAS and reverse the potassium loss associated with the diuretic.

INDICATION:

Cardoplus® 50 is indicated for the treatment of hypertension that is non responsive to monotherapy with losartan or diuretics alone. This fixed dose combination is not indicated for initial therapy of hypertension, except when the hypertension is severe enough that the value of achieving prompt blood pressure control exceeds the risk of initiating combination therapy.

DOSAGE AND ADMINISTRATION:

Dosing must be individualized. The usual initial dose is one tablet daily. It may be increased, if necessary to two tablets daily. The maximum antihypertensive effect is obtained about three weeks after initiation of therapy.

CONTRAINDICATION:

Cardoplus®50 is contraindicated in patients who are hypersensitive to either component of this product and other sulfonamide derived drugs. It is also contraindicated to the patients with anuria.

USE IN PREGNANCY AND LACTATION:

Cardoplus®50 acts directly on the renin-angiotensin system and can cause foetal and neonatal morbidity and death when administered to pregnant women during second and third trimester. Hence the combination should not be used in pregnancy. It is not known whether losartan is excreted in human milk, but significant levels of losartan and its active metabolite were shown to be present in human milk. Thiazide appears in human milk. Thus **Cardoplus® 50** should not be used by nursing mother. If its use is considered necessary, breast feeding should be avoided.

PRECAUTION:

Patients receiving **Cardoplus®50** should not use potassium supplements or salt substitutes containing potassium without consulting the prescribing physician. Inadequate fluid intake, excessive perspiration, diarrhea or vomiting can lead to an excessive fall in blood pressure, with the consequences of lightheadedness and possible syncope. Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such history. Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus.

DRUG INTERACTION:

Alcohol, barbiturates or narcotics: Potentiation of orthostatic hypotension may occur.
Antidiabetic drugs (oral agent and insulin): Dosage adjustment of the antidiabetic drug may required.
Cholestyramine and colestipol resins: Absorption of Hydrochlorothiazide is impaired in the presence of anionic exchange resin. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract up to 85 and 43 percent, respectively.
Corticosteroids/ACTH: Intensified electrolyte depletion, particularly hypokalemia may occur.
Pressor amines(e.g: norepinephrine): Response to pressor amines may be increased.
Nondepolarizing skeletal muscle relaxants: Responsiveness to the muscle relaxants may be increased.
Lithium: Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity.
Non-steroidal anti-inflammatory agents: In some patients, administration of a non steroidal anti inflammatory agent can reduce the anti hypertensive effects of **Cardoplus®50**. Patients receiving these medications concomitantly should be observed closely to determine if the desired antihypertensive effect is obtained.

SIDE-EFFECTS:

The combination of losartan and hydrochlorothiazide is well tolerable. The commonly observed side effects include headache, dizziness,, abdominal pain, asthenia/fatigue, edema, occasional increases in liver enzymes, blood urea and serum creatinine. Angioedema has been reported rarely.

PHARMACEUTICAL PRECAUTION:

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING:

Cardoplus®50 tablet: Box containing 4 strips of 10 tablets each. Each film coated tablet contains Losartan Potassium USP 50 mg and Hydrochlorothiazide BP 12.5 mg.

SK+F
Manufactured by:
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